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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,492	03/06/2002	Gudrun Schmidt	112843-036	8620
29157	7590	08/17/2004		EXAMINER
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135				MARX, IRENE
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,492	SCHMIDT ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 July 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3 and 5-16 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 7-15 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,5 and 6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

The amendment filed 7/23/04 is acknowledged. Claims 1, 3 and 5-6 are being considered on the merits.

This application contains claims 4 and 7-15 drawn to an invention nonelected with traverse in Paper filed 3/15/04. A complete reply to the final rejection must include cancellation of filed nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 4, and 7-15 are withdrawn from consideration as directed to a non-elected invention.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 5-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the treatment of *L. johnsonii* La1 with about 3.5% NaCl for 15 minutes and specific other shocks, including the limitations of claim 3 of a temperature of about 48°C for about 15 minutes. The as-filed specification recited these methods of treatment in the alternative. See specification, page 7.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3 and 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in that the treatment with NaCl appears to be osmotic shock or chemical stress. If two different treatments are intended in this context, they should be clearly set forth.

Claim 5 is confusing and fails to further limit claim 1 in the treatment with a “salt”.

Claim 6 vague and indefinite in that fails to find clear antecedent basis in claim 1 for “the stress”, since it is unclear which stress is intended. Is it the NaCl treatment. Moreover, claim 1 recites “15 minutes” and not “ and “for at least 15 minutes”. Thus claim 6 lacks clear antecedent basis for this limitation.

The rejection under 35 U.S.C 102 is withdrawn in view of applicant’s amendment.

Claims 1, 3 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrie *et al.* taken with Broadbent *et al.*, Kilstrup *et al.* and Volker *et al.*.

Carrie *et al.* disclose a method of protecting *L. johnsonii* La1 against stress by submitting the strain to a sublethal thermal shock of 43°C, followed by incubation at 38°C. See, e.g., Examples 10 and 11.

The reference differs from the claimed invention in that the reference does not specifically address a process of protecting the strain at the temperature and salt concentrations as claimed.

However, Broadbent *et al.* disclose that *Lactobacillus* strains are protected against stress by subjecting the strains to sublethal levels of heat shock at various temperatures (See, e.g., Table 1, page 14). The reference strongly suggests that induction of heat shock proteins results in thermotolerance in various *Lactobacillus* (See, e.g., page 18, paragraph 3). Therefore, one of ordinary skill in the art would also have reasonably expected this effect in protecting *L. johnsonii* La1 against stress.

In addition, Kilstrup *et al.* teach the protection of the bacteria against stress by induction of heat shock proteins in *Lactococcus* using sublethal levels of salt stress (See, e.g., page 1834) and Volker *et al.* similarly teach the induction of heat shock proteins in *Bacillus* using sublethal

levels of heat and/or salt stress to protect the microorganisms against stress due to induction of stress tolerance in the strains (See, e.g., page 2128).

In view of the universality of the heat shock response in bacteria, one of ordinary skill in the art would have had a reasonable expectation of success of protecting *L. johnsonii* La1 against stress by inducing the heat shock proteins using sublethal levels of stress, including heat stress and salt stress.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Carrie *et al.* by using different levels of sublethal temperatures and/or salt concentrations with the expectation of inducing heat shock proteins to protect the strain, as suggested by the teachings of Broadbent *et al.*, Kilstrup *et al.* and Volker *et al.* for the expected benefit of obtaining a thermotolerant and/or salt-tolerant strain which is increased in stability and shelf-life.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's contention that Carrie is non-analogous art is noted. However, applicant must consider that the same strain is treated at substantially similar conditions. Clearly the treatment constitutes a sublethal treatment. The protection against stress would be expected to be a natural result of the process at least to some extent. Applicant alleges that Carrie is deficient because they did not recognize the problem of protection against stress. However, the instant specification demonstrates reduction of stress effects only at certain conditions.

The arguments directed against Broadbent *et al.* are that this reference only discusses stress tolerance in *Lactobacillus* against heat by heat shock and thus fails to consider other tolerance inducers, "let alone salt induced heat protection for *Lactobacillus johnsonii* (La1) as required by the claimed invention". However, the claimed invention requires protection against an undefined stress, not protection against heat shock, as alleged, and the treatment as claimed includes thermal shock. It is not clear from the record that the effects of thermal and salt shock are significantly different from thermal shock alone. See also the rejection under new matter.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651